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Office of Regulatory Policy
HFD-7
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Attention: Beverly Friedman

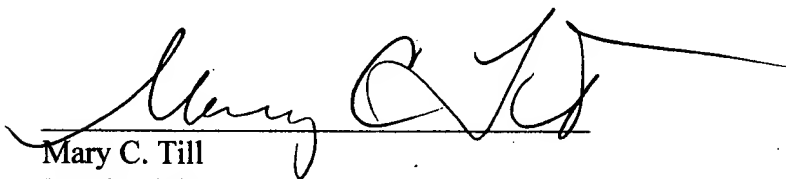
The attached application for patent term extension of U.S. Patent No. 6,884,879, was filed on August 25, 2006, under 35 U.S.C. § 156. It is noted that patent term extension applications for the same regulatory review period for the human biological product, LUCENTIS® (ranibizumab), have been filed in U.S. Patent No. 7,060,269 (as indicated in a letter to FDA mailed on April 3, 2007) and U.S. Patent No. 6,407,213.

The assistance of your Office is requested in confirming that the product identified in the application, LUCENTIS® (ranibizumab), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Applicant is advised that despite the statement in compliance with 37 C.F.R. § 1.740(a)(14) regarding payment of the applicable fee by check for submission of a patent term extension application, no check was present and no record exists of the Office cashing the check. Therefore, in accordance with the express authorization provided in the same paragraph, the fee of \$1,120 as perscribed in 37 C.F.R. § 1.20(j) is being charged to deposit account no. 18-1260.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

A handwritten signature in black ink, appearing to read "Mary C. Till", with a long horizontal line extending to the right.

Mary C. Till

Legal Advisor

Office of Patent Legal Administration

Office of the Deputy Commissioner
for Patent Examination Policy

cc: Jeffrey P. Kushan
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